This listing of claims will replace all prior versions, and listings, of claims in the application:

**LISTING OF CLAIMS:**

1. **(Currently Amended)** A directly compressible tabletting aid, comprising a xylitol content of more than 90% by weight and a content of at least one other polyol of less than 10% by weight, produced by dissolving the xylitol in a solvent and spray drying or fluidized bed ~~granulation~~ granulating.

2. **(Previously Presented)** A directly compressible tabletting aid, according to Claim 1, wherein polyols present in addition to xylitol are selected from the group consisting of mannitol and lactitol.

3. **(Previously Presented)** A directly compressible tabletting aid, according to Claim 1, wherein it is obtainable by dissolving xylitol and at least one other polyol in water and spraying the resulting aqueous mixture in a stream of air at a temperature of from 120°C to 300°C.

4. **(Previously Presented)** A directly compressible tabletting aid, according to Claim 1, wherein it is obtainable by dissolving xylitol and at least one other polyol in water and fluidizing the resulting aqueous mixture in a stream of air at a temperature of from 30°C to 110°C.

**5. (Previously Presented)** A directly compressible tabletting aid according to Claim 1, wherein the xylitol and mannitol; xylitol and lactitol; or xylitol, mannitol and lactitol are employed as polyols.

**6. (Previously Presented)** A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to mannitol is 90:10 to 98:2.

**7. (Previously Presented)** A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to lactitol is 90:10 to 98:2.

**8. (Previously Presented)** A directly compressible tabletting aid according to Claim 5, wherein the xylitol:mannitol:lactitol ratio is between 90:1:9 or 90:9:1 and 98:1:1.

**9. (Previously Presented)** A directly compressible tabletting aid according to Claim 1, wherein the water content is less than 1% by weight.

**10. (Currently Amended)** A process for producing a directly compressible tabletting aid ~~according to Claim 1~~ comprising a xylitol content of more than 90% by weight and a content of at least one other polyol of less than 10% by weight, produced by dissolving the xylitol in a solvent and spray drying or fluidized bed granulating, comprising:

a) producing an aqueous solution by dissolving xylitol and at least one other polyol, the resulting mixture having a xylitol content of more than 90% by weight based on the total polyol content,

b1) spraying the resulting mixture in a stream of air at a temperature of from 120°C to 300°C, evaporation of the water taking place, or

b2) fluidizing the resulting mixture in a stream of air at a temperature of from 30°C to 110°C, evaporation of the water taking place, and

c) isolating the tabletting aid.

**11. (Previously Presented)** A method for producing a shaped or unshaped polyol composition by melt extruding a directly compressible tabletting aid mixture according to Claim 1.

**12. (Previously Presented)** A composition or formulation comprising a directly compressible tabletting aid according to Claim 1.

**13. (Previously Presented)** A solid form or compact, comprising a directly compressible tabletting aid according to Claim 1.

**14. (Previously Presented)** A solid form or compact according to Claim 13, comprising one or more water-insoluble and/or water-soluble additions homogeneously dispersed.

**15. (Previously Presented)** A solid form or compact according to Claim 13, comprising citric acid as addition.

16. **(Previously Presented)** A solid form or compact according to Claim 13, comprising at least one active pharmaceutical ingredient, sweetener, colorant, vitamin or trace element.

17. **(Previously Presented)** A solid form or compact according to Claim 16, comprising at least one active pharmaceutical ingredient which is an analgesics or antacid.

18. **(Previously Presented)** A solid form or compact according to Claim 16, comprising at least one sweetener which is acesulfame K, aspartame, saccharin, cyclamate, sucralose or neohesperidine DC.

19. **(Previously Presented)** A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to mannitol is in a range between 90:10 to 95:5.

20. **(Previously Presented)** A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to lactitol is in a range between 90:10 to 95:5.

21. **(Previously Presented)** A tablet composition comprising more than 90% by weight xylitol and less than 10% of at least one other polyol wherein the composition is produced by dissolving xylitol and at least one other polyol and spray drying or fluidized bed granulating the resulting mixture.

**22. (Previously Presented)** A process for producing a tablet composition, comprising making an aqueous solution of xylitol and at least one other polyol, the resulting solution having a xylitol content of more than 90% by weight based on the total polyol content.

**23. (Currently Amended)** A process ~~according to claim 22~~ for producing a tablet composition, ~~the process further~~ comprising:

making an aqueous solution of xylitol and at least one other polyol, the resulting solution having a xylitol content of more than 90% by weight based on the total polyol content,

b1) spraying the resulting mixture in a stream of air at a temperature of 120°C - 300°C, evaporation of the water taking place, or

b2) fluidizing the resulting mixture in a stream of air at a temperature of 30°C - 110°C, evaporation of the water taking place, and

c) isolating the tabletting aid.

**24. (Currently Amended)** A tabletting aid according to claim 1, wherein the tabletting aid has a ~~substantially~~ homogenous solution distribution on a surface of xylitol and at least one other polyol.

**25. (Currently Amended)** A process according to claim 22, wherein the resulting solution is ~~substantially~~ homogeneous.

## (5) SUMMARY OF THE INVENTION

The invention relates to a directly compressible tabletting aid, which includes a xylitol content of more than 90% by weight and a content of at least one other polyol of less than 10% by weight (page 1, lines 3-6, and page 4, lines 31-35). The directly compressible tabletting aid is produced by dissolving the xylitol in a solvent and spray drying or fluidized bed granulation (page 1, lines 6-7, and page 4, lines 35-36).

In the past, known polyols mannitol, lactitol, isomalt and xylitol show poor tabletting characteristics, resulting in low tablet hardness, capping and high friability of the tablets. Page 2, lines 1-4.

In marked contrast, the invention relates to a directly compressible tabletting aid which is simple to produce, and has the following properties:

- improved tabletting properties by comparison with xylitol, in particular in relation to the resulting tablet hardnesses, the friability and the tendency to capping;
- improved taste-masking properties by comparison with known polyols; and
- advantageous effects on the sensory mouthfeel of the products.

Page 4, line 37 - page 5, line 11.

## (6) ISSUES

1. Whether or not claims 24 and 25 contain subject matter not described in the specification at the time of filing to satisfy 35 U.S.C. § 112, first paragraph. Particularly, does the specification support the phrases "substantially homogenous distribution" or "solution is substantially homogenous" when a solution is inherently homogenous.

2. Whether or not claims 1, 2, 4-7, 9, 12, 13, 19-21 and 24 are allegedly anticipated by U.S. Pat. No. 5,536,526 (Virtanen) when Virtanen fails to teach a directly

compressible tabletting aid, but rather a product without the characteristics of the claimed aid, composition, formulation, form or compact.

3. Whether or not claims 1, 2, 4, 5, 9, 12-16, 18, 21, 22, 24 and 25 are allegedly anticipated by U.S. Pat. No. 5,204,115 (Olinger) when Olinger fails to teach a directly compressible tabletting aid.

A. Can Olinger anticipate when it fails to teach a process for making an aqueous solution of xylitol and one other polyol?

B. Can Olinger anticipate when evidence is in the record that Olinger's product fails to have the characteristics of the claimed aid, composition, formulation, form, or compact.

4. Whether or not claims 1-9, 11-16, 18-22, 24 and 25 are rendered obvious by U.S. Pat. No. 5,958,471 (Schwarz) in view of Virtanen when:

A. there is no desirability to support their combination?

B. the present invention exhibits significant and unexpected results?

5. Whether or not claims 1, 2, 4, 5, 9, 12-18, 21, 22, 24 and 25 are rendered obvious by Olinger and U.S. Patent No. 5, 576,014 (Mizumoto) when:

A. there is no desirability to support their combination?

B. the present invention exhibits significant and unexpected results?

Applicants acknowledge the allowability of claims 10 and 23. As such, these claims are rewritten into independent form, and Applicants respectfully request that they be indicated as allowed in the next paper from the Office.

**Claim Rejections Under 35 U.S.C. § 112, first paragraph**

*Issue 1*

Claims 24-25 stand rejected as allegedly containing subject matter not described in the specification. Particularly, the Action alleges that "substantially homogenous distribution" and "solution is substantially homogenous" are not supported in the claims.

As discussed above, a solution is inherently homogenous. See attached definitions of solution (*Hanley's Condensed Chemical Dictionary* 1997), *Grant & Hackh's Chemical Dictionary* (1987), and *Webster's New World Dictionary, Second College Edition* (1984)). Consequently, Applicants are merely claiming a well-known, inherent property of a solution. Deletion of the term "substantially" should in no way be construed as acquiescence to this ground of rejection, but has been made to conform claims 24 and 25 to the provided definitions of a solution and to expedite prosecution.

**Claim Rejections Under 35 U.S.C. § 102(b)**

*Issues 2 and 3*

Claims 1, 2, 4, 5-7, 9, 12, 13, 19-21 and 24 stand rejected as allegedly anticipated by U.S. Pat. No. 5,536,526 (Virtanen) and claims 1, 2, 4, 5, 9, 12-16, 18, and 21-25 stand rejected as allegedly anticipated by U.S. Pat. No. 5,204,115 (Olinger). Applicants respectfully traverse these rejections.

A. With respect to the process claims (relevant to claims 11, 22 and 25), Applicants respectfully submit that neither Virtanen or Olinger teaches a method for producing a polyol composition by melt extruding an aid according to claim 1 (relevant to claim 11) and making an aqueous solution of xylitol and at least one other polyol (relevant to claims 22 and 25). Rather, as discussed in further detail below, Virtanen and Olinger disclose

granulating, not dissolving, xylitol. All claim limitations must be taught to anticipate. Because these features are not taught, these method and process claims are not anticipated.

B. With respect to the product claims (relevant to claims 1 and 21), Applicants respectfully submit that there is no anticipation because both the Virtanen and Olinger patents relate to granulating xylitol, not dissolving the xylitol in a solvent. Virtanen granulates xylitol crystals. As discussed in Virtanen, the granulation process involves agglomerating crystalline xylitol (ground or otherwise comminuted to a small particle size) by means of polyol based syrup (column 6, lines 25-29). Thus, a granulation process involves the mixing of two or more ingredients in a solid state and leads to inhomogeneous granules. In marked contrast, the tabletting aid of the present invention is produced by dissolving the xylitol in a solvent forming a homogeneous solution. Evaporating the solvent by spray drying or fluidized bed granulation leads to a homogenous tabletting aid. Virtanen discloses granulating xylitol with a small amount of sorbitol syrup (column 7, lines 20-25) and exemplifies introducing into a granulator 800 kg/hr of powder and 50 l/hour syrup solution (Example 2 at column 8, lines 40-46). Clearly, no solution is created.

Olinger discloses a directly compressible, non-cariogenic xylitol granulate which comprises xylitol and a binder in the range of about 0.1% to about 5% by weight, wherein the binder is physiologically acceptable, non-cariogenic and is taken from the group consisting of polymerized reducing sugars, alkali carboxymethylcellulose and hydrogenated starch hydrolysate (column 5, line 65 to column 6, line 4). In one method, an aqueous binder solution is added to milled xylitol, and the resulting granulate is dried and screened. (Column 7, lines 8-10). Thus, Olinger adds a solution to the granulate, but does not dissolve the granulate. Olinger also discloses a directly compressible granulate comprising a polyol such as mannitol, lactitol, sorbitol, isomalt and maltitol or a sweetener suitable for diabetic

applications such as crystalline fructose and/or mixtures thereof, and a polydextrose binder present in the range of about 0.1% to about 5% by weight. (Column 7, lines 16-22). Olinger exemplifies spraying 528.6 grams of polydextrose syrup on 6000 grams of xylitol. See Example 2 at column 9. Thus, a granulation process involves the mixing of two or more ingredients in a solid state and leads to inhomogeneous granules. In marked contrast, the tabletting aid of the present invention is produced by dissolving the xylitol in a solvent forming a homogeneous solution. Evaporating the solvent by spray drying or fluidized bed granulation leads to a homogenous tabletting aid. Consequently, the rejections in view of these references should be withdrawn.

The Examiner asserts that the claims do not exclude particle surfaces with a needle structure. But Applicants submit that such a structure is excluded by the process features of the claims, as discussed below. See *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

A declaration previously submitted with the preliminary amendment of July 1, 2002, provides evidence where the declarant attests to the differences between spraying a sorbitol solution onto a xylitol bed (relevant to Virtanen and Olinger) and co-spraying a xylitol-sorbitol solution onto a xylitol-sorbitol bed (relevant to the present invention). These experiments were carried out as described by Example 2 of Virtanen in order to prepare powders containing 97% of xylitol and 3% sorbitol. Moreover, the experiments were carried out using a SHUGI granulator.

As depicted in the scanning electron microscopy pictures, powders TG27/1 and TG28/1 (relevant to Virtanen and Olinger) depict particles with a needle structure. In marked contrast, powder TG31/1 (relevant to the present invention) does not show this needle structure. Rather, the surface of powder TG31/1 is composed of a mixture of sorbitol and xylitol. Consequently, the spraying techniques relevant to Virtanen and Olinger result in

different structural properties of powder particles as compared to spraying techniques of the present invention. Also, the experiments demonstrate that introducing sorbitol solution and xylitol to a granulator does not form a homogeneous solution prior to granulation. Therefore, Applicants respectfully submit that this declaration provides more than sufficient evidence to establish the unobvious and novel differences between the claimed product and the prior art product.

Moreover, the cited references in the Action support the contention that the granulates of Virtanen and Olinger are inhomogeneous. Particularly, Virtanen discloses:

> The granulation process is fundamentally different from the dry mixing of two polyols such as xylitol and sorbitol, such as that disclosed by G. B. Patent Nos. 1,526,020. **The granulation process results in the crystallization of some of the sorbitol or present onto the surface of the xylitol particles forming fine, needle like protrusions.** These needle like protrusions can be seen by electron microscopes, and a photograph showing the granulate of the present invention (with xylitol present in an amount of about 97% by weight, and sorbitol present in an amount of about 3% by weight) is shown in FIG. 1; the needle like crystals can be clearly seen. It is thought that the needle like protrusions are, or at least contribute to, the compressibility of the granulate of the present invention. Blends of xylitol and sorbitol in the proportion covered by the present invention which are simply admixed do not exhibit adequate compressibility and do not exhibit the needle like protrusions in electron micrographs such as those seen in FIG. 1.

Column 7, line 61, - column 8, line 11, emphasis added.

Thus, granulating forms sorbitol needle like protrusions on xylitol particles (an inhomogeneous composition) versus dissolving the xylitol in a solvent, which creates a homogenous composition. This clearly establishes that the prior art products do not possess the characteristics of the claimed invention derived from the process aspects. Consequently, Applicants respectfully submit that there is more than sufficient evidence in the record to

demonstrate the patentability (both novelty and unobviousness) of Applicants' invention, and these prior art rejections should be withdrawn.

**Claim Rejections Under 35 U.S.C. § 103**

*Issues 4 and 5*

A. Claims 1-9, 11-16, 18-22, 24 and 25 stand rejected as allegedly obvious by Virtanen in view of U.S. Patent No. 5,958,471 (Schwarz). Applicants respectfully traverse these rejections.

Virtanen, as discussed above, granulates xylitol crystals. Schwarz relates, at least in part, to compositions obtainable by dissolving at least two polyols in water (column 2, lines 7-8). Virtanen fails to teach the desirability of dissolving the xylitol crystals in a solvent for, after subsequent processing, creating a tabletting aid. The mere fact that references can be combined or modified does not render the resultant combination *prima facie* obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), M.P.E.P. § 2143.01. Here, Virtanen's requirement that crystals of xylitol contain a surface coating of crystals of another polyol teaches against forming a homogenous solution of xylitol and polyol prior to crystallizing. Thus, there is no motivation to combine these references. Further demonstrating the lack of motivation to combine these references, Schwarz broadly defines the suitable range of "between 50:50 and 99:1" for compositions of sorbitol and xylitol at col. 2, lines 13-15. This ratio is inconsistent with the proportions required by Virtanen, namely 94% -98% xylitol (column 5, lines 38-43). There is no teaching or suggestion to modify the composition proportions of Schwarz to make them compatible with Virtanen. Lacking this teaching, there is no motivation to support this combination of references.

Claims 1, 2, 4, 5, 9, 12-18, and 21-25 stand rejected as allegedly obvious by Virtanen in view of U.S. Patent No. 5,576,014 (Mizumoto).

At the outset, it appears that the Action is relying on Mizumoto solely to reject claim 17. It is not apparent that Mizumoto is relied upon to reject the other claims. Regardless, Mizumoto fails to cure the deficiencies in the Virtanen reference because Mizumoto's dissolving compressed molding is also made by mixing or granulating various components, *see e.g* column 7, lines 19-46. Consequently, there is no *prima facie* case of obviousness.

B. Supererogatorily, the present invention exhibits significant and unexpected results. A prima facie case of obviousness based on similarity is rebuttable by proof that the claimed invention possesses unexpectedly advantageous or superior properties. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and M.P.E.P. § 2144.09.

The Action of September 12, 2000, and the Examiner's Answer allege that there is no criticality in the amount of a particular component, *e.g.* xylitol, because the prior art obtains the same results desired by Applicants, *i.e.* a direct compressed tablet. This Action also alleges that the amount has not been shown to provide any unusual and/or unexpected results over the applied prior art.

Applicants traverses these allegations. As discussed in the present specification, comparative example 2, pure xylitol, even spray dried, does not possess the required tabletting properties. Rather, the addition of up to 10%, preferably 5-10%, of a second polyol, preferably mannitol, can achieve the desired results (see, e.g. Examples 1-4). Consequently, Applicants respectfully submit that the present invention exhibits significant and unexpected results, at least due, in part, to the disclosure in the present specification.